

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
DRG International., Inc.
841 Mountain Avenue
Springfield NJ 07081
USA

has established and applies a quality management system for medical devices
for the following scope:

Scope see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2020-11-25
Certificate Registration No.: SX 60153210 0001
An audit was performed. Report No.: 21238159 006
This Certificate is valid until: 2023-11-22

Certification Body



Date 2020-11-25



S. Hoffmann
Dipl.-Ing. Sven Hoffmann

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60153210 0001
Report No.: 21238159 006

Organization: DRG International., Inc.
841 Mountain Avenue
Springfield NJ 07081
USA

Scope: Manufacturing and distribution of in vitro diagnostic reagents used in the diagnosis of autoimmune status, cancer, cardiac markers, disease status, fertility testing, pregnancy testing, diabetes and immune status.
Installation and service of in vitro diagnostic analyzers.

Certification Body



Date: 2020-11-25



Dipl.-Ing. Sven Hoffmann